

Bone Therapeutics receives EUR 1.0 million to advance ongoing JTA-004 phase III knee osteoarthritis study

Recruitment on track with 164 patients already treated

Gosselies, Belgium, 13 August 2020, 7am CEST – BONE THERAPEUTICS (Euronext Brussels and Paris: BOTHE), the cell therapy company addressing high unmet medical needs in orthopedics and bone diseases, today announces it has been granted EUR 1.0 million in non-dilutive funding from the Directorate-General for Economy, Employment and Research of the Walloon Region, Belgium. This funding will provide further financial support to Bone Therapeutics, in addition to recent financing, to advance its current pivotal phase III clinical study with the enriched protein solution, JTA-004.

The JTA-004 phase III study is a controlled, randomized, double-blind trial. It is evaluating the potential of a single, intra-articular injection of JTA-004 to reduce osteoarthritic pain in the knee compared to placebo or Hylan G-F 20, the leading current osteoarthritis treatment on the market. The study is being conducted in six European countries as well as Hong Kong SAR. Since the initiation of the trial in mid-May 2020, 164 patients have already been treated, roughly 20% of the targeted assessable patients. At the current recruitment rate, Bone Therapeutics expects to complete patient enrolment before year-end and anticipates reporting topline results on the 3-month primary endpoint and 6-month follow-up period in the second half of 2021.

“The continued support of Bone Therapeutics by the Directorate-General for the Economy, Employment and Research of the Walloon Region, and especially the

● **Le communiqué de presse [en français](#)**

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Department SPW-Research, has been very important to advancing our program of orthopedics and bone disease therapies,” said **Miguel Forte, MD, PhD, Chief Executive Officer of Bone Therapeutics**. “This specific financial support will provide additional assistance in further advancing our phase III trial in knee osteoarthritis and will add extra momentum to discussions with potential business partners. The successful completion of this study aims at confirming the safety and efficacy of JTA-004 towards commercialization as a potential new and much-needed treatment option for this large patient population.”

The non-dilutive funding is granted under the form of ‘avances récupérables’ to support specific research and development programs and is subject to suspensive conditions. Under the applicable conditions, the funding is reimbursable over the economic life of the project (25 years). Thirty per cent is refundable based on a fixed reimbursement schedule, while the balance is refunded under the form of royalties over the same period.



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● About JTA-004

JTA-004 is Bone Therapeutics’ next generation of intra-articular injectables for the treatment of osteoarthritic pain in the knee. Consisting of a unique mix of plasma proteins, hyaluronic acid - a natural component of knee synovial fluid, and a fast-acting analgesic, JTA-004 intends to provide added lubrication and protection to the cartilage of the arthritic joint and to alleviate osteoarthritic pain. In a phase II study involving 164 patients, JTA-004 showed an improved pain relief at 3 and 6 months compared to Hylan G-F 20, the global market leader in osteoarthritis treatment.

● About Knee Osteoarthritis

Osteoarthritis (OA), also known as degenerative joint disease, is the most common chronic joint condition in which the protective cartilage in the joints progressively break down resulting in joint pain, swelling, stiffness and limited range of motion. The knee is one of the joints that are mostly affected by osteoarthritis, with an estimated 250 million cases worldwide.

The prevalence of knee osteoarthritis (KOA) is expected to increase in the coming years due to increasingly aging and obese population. Currently, there is no cure for KOA and treatments focus on relieving and controlling pain and symptoms, preventing disease progression, minimizing disability, and improving quality of life. Most drugs prescribed to KOA patients are topical or oral analgesics and anti-inflammatory drugs. Ultimately, severe KOA lead to highly invasive surgical interventions such as total knee replacement.

● About Bone Therapeutics

Bone Therapeutics is a leading biotech company focused on the development of innovative products to address high unmet needs in orthopedics and bone diseases. The Company has a broad, diversified portfolio of bone cell therapies and an innovative biological product in later-stage clinical development, which target markets with large unmet medical needs and limited innovation.

Bone Therapeutics is developing an off-the-shelf protein solution, JTA-004, which is currently in

phase III development for the treatment of pain in knee osteoarthritis. Consisting of a unique mix of plasma proteins, hyaluronic acid - a natural component of knee synovial fluid, and a fast-acting analgesic, JTA-004 intends to provide added lubrication and protection to the cartilage of the arthritic joint and to alleviate osteoarthritic pain. Positive phase IIb efficacy results in patients with knee osteoarthritis showed a statistically significant improvement in pain relief compared to a leading viscosupplement.

Bone Therapeutics' other core technology is based on its cutting-edge allogeneic cell therapy platform (ALLOB) which can be stored at the point of use in the hospital, and uses a unique, proprietary approach to bone regeneration, which turns undifferentiated stromal cells from healthy donors into bone-forming cells. These cells are produced via a proprietary, scalable cutting-edge manufacturing process. Following the CTA approval by regulatory authorities in Europe, the Company is ready to start the phase IIb clinical trial with ALLOB in patients with difficult tibial fractures, using its optimized production process.

The ALLOB platform technology has multiple applications and will continue to be evaluated in other indications including spinal fusion, osteotomy, maxillofacial and dental applications.

Bone Therapeutics' cell therapy products are manufactured to the highest GMP (Good Manufacturing Practices) standards and are protected by a broad IP (Intellectual Property) portfolio covering ten patent families as well as knowhow. The Company is based in the BioPark in Gosselies, Belgium. Further information is available at www.bonetherapeutics.com.

Certain statements, beliefs and opinions in this press release are forward-looking, which reflect the Company or, as appropriate, the Company directors' current expectations and projections about future events. By their nature, forward-looking statements involve a number of risks, uncertainties and assumptions that could cause actual results or events to differ materially from those expressed or implied by the forward-looking statements. These risks, uncertainties and assumptions could adversely affect the outcome and financial effects of the plans and events described herein. A multitude of factors including, but not limited to, changes in demand, competition and technology, can cause actual events, performance or results to differ significantly from any anticipated development. Forward looking statements contained in this press release regarding past trends or activities should not be taken as a representation that such trends or activities will continue in the future. As a result, the Company expressly disclaims any obligation or undertaking to release any update or revisions to any forward-looking statements in this press release as a result of any change in expectations or any change in events, conditions, assumptions or circumstances on which these forward-looking statements are based. Neither the Company nor its advisers or representatives nor any of its subsidiary undertakings or any such person's officers or employees guarantees that the assumptions underlying such forward-looking statements are free from errors nor does either accept any responsibility for the future accuracy of the forward-looking statements contained in this press release or the actual occurrence of the forecasted developments. You should not place undue reliance on forward-looking statements, which speak only as of the date of this press release.